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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,777	11/26/2003	Bruce Kevin Wagoner	4237-101	9677

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,777	WAGONER, BRUCE KEVIN	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6 and 8-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *17* is/are allowed.

6)☒ Claim(s) *2-6, 8-16 and 20-48* is/are rejected.

7)☒ Claim(s) *18 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/06 has been entered.

Claims 2-6 and 8-48 are pending in the application and were examined on their merits.

The rejections over Brasher (2001) , Krzysik and Wu et al. are removed due to the cancellation of claims 1 and 7 and the new claim dependencies. Thus, arguments pertaining to these rejections are rendered moot.

Applicant's arguments pertinent to the new rejections were considered and a response proceeds the rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Flick (2001) in light of Garcia et al. (2005)*.

Flick (2001) disclosed a sun protection cream for babies which included; *inter alia*, shea butter, urea, safflower oil and castor oil (oxidation-stable natural oil) absent any parabens (p. 17). Pertaining to claim 32, it is noted that safflower oil contains steroid alcohols (sterols) as evidenced by Garcia et al. (see Abstract).

Further, it is newly deemed that absent any indication what is or is not excluded by the phrase 'consisting essentially of', claim 41 is given it's broadest interpretation and deemed to be equivalent to 'comprising'.

*This reference is cited merely to relay an inherent property and is not used in the basis for rejection *per se*.

Claim Rejections - 35 USC § 103

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flick (1989).

Flick (1989) disclosed an anti-wrinkle cream which included; *inter alia*, hybrid sunflower seed oil and Rovisome-AHA (lactic acid).

Flick did not specifically state that ammonium lactate was present in the composition.

One of ordinary skill in the art would have been motivated to substitute the lactic acid in the composition for ammonium lactate because ammonium lactate is simply the ammonium salt of the lactic acid. Therefore, one of ordinary skill in the art would have had a reasonable expectation that ammonium lactate would have been an equivalent substitution for lactic acid.

Claims 2-6 and 8-16 and 20 -48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huard et al. (US 6,485,733 B1) in view of Nagel (1977) in view of Quan et al. (US 6,180,133 B1) in view of Durr et al. (US 5,997,889) in view of Hill et al. (US 4,233,295) in view of McNulty et al. (US 2005/0048105 A1).

To reiterate from the previous Office Action, Huard et al. (US 6,485,733 B1) disclosed that the ingredients of Vaseline ™ Intensive Care Extra Strength Lotion included, *inter alia*, sunflower seed oil, soya sterol, glyceryl stearate, stearic acid, triethanolamine, glycerine, water, lecithin, tocopherol acetate, retinyl palmitate, disodium EDTA and urea (see col. 18, lines 51-63).

Huard et al. did not discuss the omission of parabens from Vaseline ™ Intensive Care Extra Strength Lotion or the incorporation of shea butter, ammonium lactate, butylated hydroxytoluene or sodium polyacrylate into the Vaseline ™ composition, nor did they discuss a composition consisting essentially of or comprising agents such as glycerin and shea butter.

It is well known in the art that people suffer from paraben allergies. Nagel et al. (1977) for example, reported paraben allergies to be on the rise, indicating that about 3% of the population had a topical paraben allergy (see p. 1594, column 1). Nagel et al. urged the indiscriminate use of parabens as preservatives "especially not in medicines frequently given to the allergic or potentially allergic patient" (see p. 1595, column 3).

Quan et al. (US 6,180,133 B1) teaches that studies indicated that addition of ammonium lactate to lotions had proven moisturizing activity (col. 3, line 64- col.4, line 17).

Durr et al. (US 5,997,889) disclosed that shea butter may be added to a lotion to improve its moisturizing ability (see Abstract for example).

Hill et al. (US 4,233,295) teaches that butylated hydroxytoluene, an antioxidant, is advantageous to incorporate into creams, lotions or ointments in order to preserve the active ingredients therein (see col. 6, lines 23-26).

McNulty et al. (US 2005/0048105 A1) teaches that sodium polyacrylate is a known thickening agent for creams and lotions[0069].

One of ordinary skill in the art would have been motivated to formulate Vaseline ™ Intensive Care Extra Strength Lotion without parabens in order to manufacture a topical moisturizing product which was safe for persons allergic to paraben preservatives. It was clear from the prior art that a percentage of the population was allergic to topically-applied compositions comprising parabens. Therefore, the ordinary artisan would have been motivated to create paraben-free forms of known topical compositions in order to meet the demands of the public.

One of ordinary skill in the art would have been motivated to combine ammonium lactate and shea butter into the Vaseline ™ composition because they are ingredients well known to improve moisture to the skin. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for lending moisture protection to the skin. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

One of ordinary skill in the art would have been motivated to incorporate butylated hydroxytoluene to the Vaseline ™ composition in order to preserve the active ingredients therein. It was clear from the prior art that butylated hydroxytoluene was used as an antioxidant in creams and lotions. Thus, the ordinary artisan would have had a reasonable expectation that the addition of this ingredient would have afforded the Vaseline ™ lotion a longer shelf-life. Further, the substitution of butylated hydroxytoluene for methylparaben would have been advantageous in the formulation of a product which was free from paraben-allergen containing ingredients.

One of ordinary skill in the art would have been motivated to add sodium polyacrylate to the Vaseline ™ composition, or alternatively, to substitute sodium polyacrylate for another thickener in Vaseline ™ such as glycerine because the addition of thickening agents to lotions imparts a thicker viscosity to the lotion which has a pleasant consistency and further is easy to administer to the skin and these thickening agents are considered functional equivalents as they perform the same function; thickening the lotion.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the cosmetic and pharmaceutical arts. One of ordinary skill in the art would have been motivated to have modified the proportions of ingredients in the lotion in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment (e.g., regular strength –vs- extra strength). Such variations in amounts of cosmetically/ pharmaceutically active ingredients is considered merely optimization of result effective variables, conventional practice in the art of pharmacology.

It is clear from the prior art cited herein that shea butter and ammonium lactate were both well known skin moisturizing ingredients (see Quan et al. and Durr et al.). Therefore, one of ordinary skill in the art would have been motivated to combine these ingredients either alone (consisting of) or with inert carriers (consisting essentially of) or combined with other moisturizing ingredients (comprising) because, again, mixing two (or more) components which are useful for the same purpose is considered obvious. One of ordinary skill in the art would have had a reasonable expectation that the combination of shea butter and ammonium lactate (for example) either alone, or with inert carriers or with other active moisturizing ingredients would have provided for moisturizing effects when administered topically because each ingredient is known to be used in skin care ingredients.

One of ordinary skill in the art would have been motivated to adjust the pH of the dermatological composition in order to manufacture products for different purposes; e.g., as a skin moisturizer or as a cleanser for example.

Applicant's arguments were fully considered, but not found persuasive for the following reasons:

Applicant argues that Huard et al. neither teaches nor suggests a composition containing a humectant such as one of urea and ammonium lactate and do not suggest a composition free of parabens (p. 16, Remarks). In response to applicant's arguments

against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that "Nagel et al. does not teach or suggest a composition that contains a humectant including at least one of urea and ammonium lactate, nor a composition that is free of parabens...there is no motivation to combine this teaching with the composition of Huard et al. based on the actual content of the references". (pp. 16-17, Remarks) Applicant further argues that Nagel et al. "does not provide support for eliminating parabens from topical composition...Nagel et al. teaches the opposite, that a patient with a known paraben allergy when the paraben is administered intravenously may have not allergy to administration of parabens (p. 17, Remarks).

The Examiner respectfully disagrees. Nagel et al., taken as a whole, clearly teaches that creating formulations without parabens would be advantageous for people with paraben allergy: "This case of immediate hypersensitivity to methylparaben and propylparaben demonstrates that parabens should not be used indiscriminately as preservatives, especially not in medicines frequently given to the allergic or potentially allergic patient" (p. 1995). It is not accepted that 'Nagel et al.' teach the opposite in that Applicant indicates that "a patient with a known paraben allergy when the paraben is administered intravenously may not have an allergy to administration of parabens" '.

The Examiner cannot clearly understand what Applicant is contending here because the patient in Nagel et al. had not been diagnosed with a paraben allergy prior to hospitalization; however, was diagnosed after hospitalization. Re-administration after four days with the hydrocortizone + parabens "induced bronchospasm" and therefore confirmed allergy to parabens. Thus, taken as a whole, the reference clearly establishes the need for paraben-free "drugs, foods and cosmetics" (p. 1995) for people who have been diagnosed with paraben allergies.

Applicant argues that Nagel et al. "shows the unpredictability of paraben allergies...one of skill in the art would not have had motivation to combine the teachings of Nagel et al. with the composition of Huard et al. The Examiner respectfully disagrees. Again, the Nagal et al. reference clearly teaches that people with known paraben allergies should sustain from the use of parabens. One of ordinary skill in the art would have been motivated to formulate Vaseline™ without parabens to enable persons with known paraben allergies to use Vaseline™ .

Applicant further argues that the combination of the references "do not teach the elements missing from the combination of the Huard et al. and Nagal et al. references"...none of the cited references taken in combination with one another teaches or suggests a composition that comprises urea or ammonium lactate and that is free of parabens or any composition that is free of parabens (pp. 17, 18 Remarks). Applicant's arguments are not convincing especially in light of the rejections under 35

USC 102(b) *supra*. It further remains deemed that the inclusion of known skin-care ingredients in order to form a skin care composition was well within the purview of the ordinary artisan at the time the invention was made. One would have been motivated to add varying moisturizing agents in order to formulate a skin care ingredient with additive effects on moisturizing. Again, the ordinary artisan would have been motivated to create products without parabens for persons with known paraben allergies. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Claim 17 is allowed.

Claims 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

December 20, 2006